

REMARKS

Continued prosecution and reconsideration of the above-identified application is respectfully requested in view of the present Reply and Amendment.

This Reply and Amendment have been made to put this application in condition for immediate allowance. It is believed that no new issues have been raised which require a further search.

I. The Amendments

Claims 1-31 have been canceled. New Claims 32-69 are presented, the subject matter of which was disclosed in the originally-filed claims and previously amended claims, and is substantively a subset thereof, redrafted for clarity. New claims 32-69 are directed toward specific embodiments of the previously-disclosed invention, and are further supported in the Examples of the invention in the specification. It is thus seen that no new matter has been presented through the requested amendments. Claims 32-69 are in the case and are before the U.S. Patent Examiner.

II. Sequence Listing

A new copy of the computer-readable form of the Biological Sequence Listing filed April 8, 2003 is enclosed to comply with the U.S. Patent Office rules of practice. The diskette containing the Biological Sequence Listing computer-readable form (CRF) accompanies this Reply and Amendment with Sequence Listing CRF and Statement.

The paper copy of the substitute Sequence Listing required under 37 C.F.R. § 1.821(c) was filed on April 8, 2003, as required under 37 C.F.R. § 1.825(a). The present substitute CRF contains only subject matter filed at that time, which was included in the original national phase filing papers under 37 C.F.R. § 371 filed January 14, 2002. The Sequence Listing has the same disclosed subject matter as the above-referenced International Patent Application, and thus does not include matter which goes beyond the disclosed in the international application as filed.

Pursuant to 37 C.F.R. § 1.825(b), a substitute copy of the computer readable form (CRF), required by 37 C.F.R. § 1.821(e), is provided.

As required under 37 C.F.R. § 1.821(f), the sequence listing information recorded in the accompanying CRF is identical to the sequence listing information recorded in the written paper copy of the "Sequence Listing" filed April 8,

2003.

It is respectfully submitted that the present application is in complete compliance with the Biological Sequence Listing requirements of 37 C.F.R. § 1.821 *et seq.*

III. Election

The restriction of the now-canceled Claims 1-31 was made final in the Office Action mailed July 1, 2003. The new claims presented herewith were drafted in compliance with that restriction requirement. It is believed that the newly presented claims clarify the claimed subject matter and are within the boundaries of the restriction requirement. The comments from Examiner Myers in our telephone conference of September 23, 2003 regarding the restriction are gratefully acknowledged. The Examiner is thanked for the helpful discussion and suggestion regarding working within the boundaries of this restriction.

IV. Title of the Invention

The title was objected to for being insufficiently descriptive of the invention. The present amendment includes a new title for the patent application, "Sequences for the

Detection of *Escherichia coli*". It is believed that this amendment overcomes the objection to the original title.

V. The Rejections

1. Rejections under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph

Claims 1-31 stood rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide enablement for any nucleic acid that encodes all or part of a flagellin protein with the expectation that the nucleic acid does not encode flagellin proteins expressed by *E. coli* H1, H7, H12 or H48 strains.

The present amendment cancels claims 1-31 and presents new claims directed toward a subset of the earlier subject matter, in the interests of speeding prosecution and obtaining claims of specific interest to the present inventors. We reserve the future right to prosecute in a continuing patent application the subject matter no longer being prosecuted as a result of the present amendment.

It is believed that new claims address obviate this basis for rejection of the claims. In view of this amendment, it is respectfully requested that the rejection of

the claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

2. Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph

Claims 1-31 stood rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1-31 were rejected as indefinite over the recitation "capable of identifying". The new claims in the present amendment avoid this ground of rejection by clearly identifying what is being detected in each method claim.

Claims 6 and 31 were rejected because it was unclear whether the nucleic acid positions referred to in the table listing "Positions of Primer 1" and "Positions of Primer 2" referred to the primers themselves. In the new claims, particularly new Claim 39, the reference to the primer is more clear.

Claims 7-21 and 26-29 were allegedly indefinite over the recitation of "detecting the H serotype of E. coli" and "detecting the H and O serotype of E. coli", because it was unclear as to whether the presence of an E. coli with an

H and/or O serotype was being claimed, or the detection of the H and/or O serotype of E. coli in a sample. New claims 40-56 and 62-65 avoid this ground of rejection.

Claims 7 and 8 were allegedly indefinite due to recitation of "detecting a nucleic acid molecule which is hybridized to the gene" as unclear as to whether the nucleic acid was the same or different from the nucleic acid of step (a). This ground for rejection is obviated in the new claims (see, e.g. new claims 40, 41, 43 and 44).

Claims 9, 10, 26 and 27 were rejected for lack of antecedent basis for "a pair of nucleic acid molecules according to claim 1". It is believed that this ground of rejection will not apply to the new claims (see, e.g. new claims 40, 41, 43 and 44).

Claims 11-14 were rejected as indefinite over recitation of "the nucleic acid molecule to hybridise to the gene". This language has not been carried forward into the new claims.

Claim 13 was rejected as indefinite regarding the sequence of the primers and the relationship between the sequences of claims 12 and 13, and unclear as to whether the primers consist of or comprise the stated sequence. Please

compare, for example new claims 46-48, 50-52 and 58-61. It is believed that the present claims are more definite.

Claims 19-21 and 25 were rejected as incomplete for omitting essential elements due to reciting detecting H and O serotypes yet only reciting a step that identifies the H serotype. Please refer to new claims 46-54. It is believed that the present claims are more definite.

Claims 24-25 were rejected as indefinite and confusing regarding the definition of the recited nucleic acid, i.e. whether it is consisting of, comprising of or derived from, for example, nucleotides 739-1932 of SEQ ID NO:45. Please refer to new claims 58 and 59. It is believed that the present claims are more definite and less confusing.

In view of the present amendments, it is respectfully requested that this ground for rejection of the pending claims under 35 U.S.C. § 112, second paragraph, be withdrawn.

3. Rejections under 35 U.S.C. § 102(b)

Claims 1-5 stood rejected under 35 U.S.C. § 102(b) as being anticipated by Fields (*Journal of Clinical*

*Microbiology*, 35:1066-1070 (May 1997)), teaching PCR amplification of the *fliC* gene of various H serotypes of *E. coli*, e.g. H5, H29, H56, H36, H53, H51 and H44.

Claims 1 and 3 stood rejected under 35 U.S.C. § 102(b) as being anticipated by Ratiner (*Journal of Bacteriology*, 180:979-984 (Feb. 1998)), teaching *E. coli* flagellin *Fla* and *flmA* genes from serotypes H44, H54 and H55.

The present claims do not include the full scope of the subject matter that had appeared in Claims 1-5, now cancelled. The present claims specifically recite the nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:13, or a portion thereof. The recited sequence is not taught or suggested by the relied-upon art.

In view of the present amendment, it is respectfully requested that these grounds for rejection of the pending claims under 35 U.S.C. § 102(b) be withdrawn.

3. Rejections under 35 U.S.C. § 103(a)

Claims 22 and 23 stood rejected under 35 U.S.C. § 103(a) as being obvious. Claim 22 was rejected as obvious over the disclosures of Fields (*Journal of Clinical Microbiology*, 35:1066-1070 (May 1997)) in view of Ahren (*The*



*Scientist*, **19**(155):20-24 (July 1995)). Claim 22 was rejected as obvious over the disclosures of Ratiner (*Journal of Bacteriology*, **180**:979-984 (Feb. 1998)) in view of Ahren (*The Scientist*, **19**(155):20-24 (July 1995)). Claim 23 was rejection as obvious over the disclosures of Fields (*Journal of Clinical Microbiology*, **35**:1066-1070 (May 1997)) in view of Ahren (*The Scientist*, **19**(155):20-24 (July 1995)) and further in view of Stevenson (*Journal of Bacteriology*, **176**:4144-4156 (1994)). Claim 23 was rejection as obvious over the disclosures of (*Journal of Bacteriology*, **180**:979-984 (Feb. 1998)) in view of Ahren (*The Scientist*, **19**(155):20-24 (July 1995)) and further in view of Stevenson (*Journal of Bacteriology*, **176**:4144-4156 (1994)).

The present claims specifically recite the nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:13, or a portion thereof. The recited sequence is not taught or suggested by the relied-upon art.

In view of the present amendment, it is respectfully requested that these grounds for rejection of the pending claims under 35 U.S.C. § 103(a) be withdrawn.

**SUMMARY**

The previously pending claims were canceled and new claims presented, and the title of the invention has been amended. It is believed that the new claims are within the scope of the restriction that had been made final, and that they obviate the previously stated grounds for rejection. The bases for objection to or rejection of the pending claims have been dealt with and made moot or otherwise overcome.

The application is believed to be in condition for allowance of the new claims. An early notice to that effect is earnestly solicited.

This Reply and Amendment with Sequence Listing CRF and Statement is accompanied by the fee required for the accompanying Petition under 37 C.F.R. § 1.136(a). No further fee is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition. This authorization is also included in the Petition under 37 C.F.R. § 1.136(a), which is provided in duplicate.

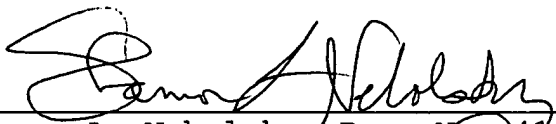
The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

REPLY AND AMENDMENT filed December 31, 2003

U.S. Serial No. 09/701,132

REMARKS

Respectfully submitted,

  
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Enclosures:

Petition and its fee  
Diskette  
Return Postcard

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**CERTIFICATE OF EXPRESS MAILING**

I hereby certify that this Reply under 37 C.F.R. § 1.116 and Amendment is being deposited with the United States Postal Service Express Mail Service with sufficient postage as Express Mail envelope with Label No. EV 337104214 US addressed to: Mail Stop \_\_\_\_\_, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on December 31, 2003.

  
Shannon L. Nebolsky